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Finerenone for CKD in Type 1 Diabetes: Updates from FINE-ONE

Dr. McGill:
You're listening to *Heart Matters* on ReachMD, and this is an *AudioAbstract*. I'm Dr. Janet McGill, and today, we'll be discussing the burden of chronic kidney disease in patients with type 1 diabetes and updates from the FINE-ONE trial, which evaluated the use of finerenone in this population.

To start, chronic kidney disease, or CKD, is a devastating complication of type 1 diabetes. It affects about 30 percent of individuals with type 1 diabetes, and its prevalence increases with age. Those who develop CKD often face additional comorbidities. Nearly 90 percent have hypertension, and more than half have either heart failure or atherosclerotic cardiovascular disease. Furthermore, individuals with type 1 diabetes and CKD are at risk for progressive loss of kidney function and end-stage kidney disease. Together, these data highlight a significant unmet need for patients with type 1 diabetes and chronic kidney disease.

Because of this high burden, patients with type 1 diabetes are recommended to have testing for urine albumin-to-creatinine ratio, or uACR, at least annually. Early changes in kidney function can be detected by rising albuminuria, often occurring before a decline in eGFR is noted. And these early increases meaningfully affect cardiovascular risk.

That being said, unlike in type 2 diabetes, where the four pillars of CKD management include renin-angiotensin system inhibitors, SGLT2 inhibitors, GLP-1 receptor agonists, and non-steroidal mineralocorticoid receptor antagonists, patients with type 1 diabetes have largely been excluded from clinical trials of these newer agents. As a result, they have not benefited from the many recent therapeutic advances for CKD risk reduction.

In fact, the last drug shown to improve CKD outcomes in type 1 diabetes was the ACE inhibitor captopril. The study was published in 1993. This underscores the purpose of FINE-ONE: to assess the efficacy and safety of the nonsteroidal mineralocorticoid receptor antagonist finerenone in patients with CKD and type 1 diabetes.

Now, let's take a closer look at FINE-ONE. It's a global, randomized, double-blind, placebo-controlled phase 3 trial conducted in adults with type 1 diabetes and chronic kidney disease characterized by elevated albuminuria. The study examined whether adding finerenone to the standard-of-care—which is glucose control and ACE inhibitors or ARBs—could further reduce uACR over six months. The results showed that it did. Finerenone reduced uACR by 25 percent compared to placebo, successfully meeting the primary endpoint of the trial.

Rates of treatment-emergent adverse events were similar between groups. As expected, hyperkalemia occurred more frequently with finerenone, about 10 percent, versus 3.3 percent with placebo, resulting in a 1.7 percent discontinuation rate.

Taken together, these findings show that finerenone is both safe and effective in reducing uACR among patients with type 1 diabetes and chronic kidney disease. It's the first therapy since the 1990s to demonstrate positive results in this population, offering a much-needed addition to the limited treatment options available to slow progressive kidney decline.

The data also support the use of uACR reduction as a bridging biomarker, and the study will be taken to FDA to seek approval of finerenone as a disease-modifying therapy for CKD and type 1 diabetes.

This has been an *AudioAbstract* for *Heart Matters*, and I'm Dr. Janet McGill. To access this and other episodes in our series, visit ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening.